**CLINCIAL LABORATORY, BLOOD BANK AND TISSUE BANK ADVISORY COMMITTEE MEETING**
**GDHR Public Health Laboratory**
**Decatur, Georgia**

**DATE: July 13, 2006**

**Attendance**: **Members:** Patrick Godbey, MD – Chairperson, Joeline Davidson, CLS(NCA), Linton Kuchler, M.D., Hattie Gallon MLT(AMT), Susan Roman, M.MSc. Larry Steed, Georgia Hospital Assoc; Alternates: Cahty Minish, CLS(NCA), Elizabeth K. Leibach, CLS, MT(SBB), Ed.D.
**DHR/ORS:** Nina J. Edidin, Esq., ORS Legal Council, Carol Zafiratos, Director Health Care Section, Ruby Durant, Deputy Director Health Care Section, Jeannie Arnold, Program Director Diagnostic Services Unit, Elizabeth Franko, Ph.D., Georgia Public Health Laboratory
**Guests:** Catherine Weaver, WellStar Health System, Myria Jackson, DeKalb Medical Center, Diane Ricotta, CDC, Katrina Knight-Farley, MCCG, E. Darcell Thaxton, MCCG
**Absent**: **Members**: Carletta Durham, MT (AMT), James Ritchie, Jr., Ph.D.

**Recorder:** Jeannie Arnold

| ITEM | DISCUSSION | ACTION/RESPONSIBILITY | DUE DATE |
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| 1 –Call to Order & Introductions | Dr. Godbey presided over introductions and called the meeting to order. | All attendees introduced themselves | |
| 2 –Minutes of May 11, 2006 Advisory Committee meeting | Minutes were reviewed and accepted with one correction. | An addition was made to item (g), Old Business, clarifying the roles of the laboratory council chairperson and Department in formulating agendas for council meetings.<br><br>Minutes were approved. | Minutes will be posted on the ORS website with the correction by August 11, 2006. |
| 3 –Old Business | **a) Laboratory Rules and Regulations Revision**<br>Jeannie Arnold requested a subcommittee be established since she received no comments/recommendations concerning the review and revision of the quality control regulations.<br><br>**b) Laboratory Council Meetings**<br>Nina Edidin, legal representative of the Department, discussed the Open Meetings Act. She informed the committee that there must be an agenda in order to conduct a meeting. The agenda must be posted at the meeting site for review by the public at least 24 hours prior to the meeting. The agenda is also posted on the ORS website at least seven days in advance of the meeting. Agenda items may be added to the posted agenda. The Deputy Director of the Health Care Section suggested that if the items on the agenda were not vital or substantive, the meeting should be cancelled.<br>The council stated that there should always be items on the agenda, especially Department information. | Cathy Weaver, Myria Jackson and Susan Roman volunteered to work with the Department. Dr. Ritchie was suggested as a source for review of Chemistry regulations.<br><br>Department will develop the agenda in concert with the Chairperson at least 2 weeks prior to meeting and assure the agenda is posted on the ORS website. Jeannie Arnold will email the agenda to the person coordinating the meeting site so the agenda can be posted at the site at least 24 hours prior to the meeting. | Sub-committee report will be presented at September meeting.<br><br>Ongoing |

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| 3 –Old Business Con't | **c) Revised Personnel Regulations**<br>This item was not on the agenda; however, the council initiated a discussion of the revision of personnel regulations. The council stated that their input was not heard or incorporated into the draft rules revisions. The Department's legal advisor stated that the regulations put forth by the Department must meet the intent of the law; therefore, some comments may not be incorporated into revisions. The role of the council as advisory versus the role of the Department as rule making was discussed. Council members were advised that the proposed rules were in the public comment phase and that they could still submit comments for consideration by the Department<br><br>Post meeting note: All council members were sent a second copy of the March 10th minutes which reflected the committee's review and vote of approval of the rules revision with only two typographical changes to be made. | Department will review and respond to public comments. | August, 2006 |
| 4 –New Business | Jeannie Arnold presented the following reports related to Laboratory survey activities<br><br>**a) <u>Data Reports, 2005 to June 2006:</u>**<br>• Number labs inspected - 199<br>• Number of Deficiencies by category – 162 deficiencies in 18 different categories. The most frequently cited deficiencies were General Quality Control (maintenance, quality control, temperatures, remedial action review, quality assessment, validation and calibration/ recalibration. Proficiency testing was the second most cited deficiency.<br>• Number of Adverse Actions – 1<br>• Complaint data – 10 complaints (3 substantiated)-<br>Complaints related to safety issues, personnel and quality.<br>• Number of off-site surveys conducted – 290<br><br>**b) <u>Survey Procedures Report:</u>**<br>• Monitoring personnel requirements – Personnel qualifications are currently monitored during on-site visits.<br>• Monitoring CLT/MT's without supervision - The surveyor will review records of all individuals which the facility lists as testing without direct on-site supervision. A random sampling of logs will be reviewed to ensure that individuals testing without direct on-site supervision have the required credentials, experience, and competency for the actual tests they are performing. | No action required | |

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| 4 –New Business Con't | • Point of Care supervision compliance – Surveying for POC compliance has not changed. Records, personnel competency, and quality assessment are reviewed. Only 1 POC deficiency was cited, which was pertaining to personnel. | | |
| 5 –Adjourn | The next meeting was set for September 14, 2006 at 10:00am at the GDHR Public Health Laboratory.<br>The motion was made and second to adjourn the meeting.<br><br>Post Meeting Note: The meeting date was changed to September 28, at 10:00 a.m. due to a CLIA mandatory training program that ORS staff must attend. | | |